K011394 JUN 2 9 2001

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Name:.....3M ESPE AG

Street:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State:.....Bavaria

Country:.....Germany

Establishment Registration Number:.9611385

Contact:.....Dr. Andreas Petermann
Manager U.S. Regulatory Affairs

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Date:.....May 04, 2001

Name of Device

Proprietary Name:.....LAVA™ Frame
LAVA™ Frame Shade
LAVA™ Ceram

Classification Name:.....Porcelain powder for clinical use

Common Name:.....All-ceramic core material
All-ceramic overlay material

Predicate Devices

IPS Empress.....K 913372 (Ivoclar)

Willi Geller Creation Porcelain .....K 981490 (Jensen Industries)

IPS Empress 2.....K 982616 (Ivoclar)

Denzir.....K 984201 (Dentronic)

OPC 3G All-ceramic system .....K 994435 (Jeneric Pentron)

DC Zirkon .....K 001815 (Austenal)

Willi Geller Creation & AV Porcelain .K 002041 (Jensen Industries)

Willi Geller Creation & LF Porcelain ..K 002904 (Jensen Industries)

Description for the Premarket Notification

The LAVA™ System is intended to fabricate all-ceramic dental devices like definite crowns and bridges. The LAVA™ System consists of three different materials:

LAVA™ Frame is a core material made of zirconia. It is provided as pre-sintered, unfashioned blanks ready to be processed in a milling device called LAVA™ Form.

LAVA™ Frame Shade is a stain solution containing pigments to color roughly the core made of LAVA™ Frame.

LAVA™ Ceram is an all-ceramic overlay material used to provide esthetics and characterization of the crown or bridge.

LAVA™ dental restorations are fabricated according to a dental impression which is scanned into a computing device. By CAD/CAM technology unfashioned zirconia blanks of LAVA™ Frame are milled in the LAVA™ Form device. After the dental appliance has been milled the piece is baked in a furnace called LAVA™ Therm. For esthetic reasons, the ceramic bridge or crown, resp. is veneered by LAVA™ Ceram.

All chemical ingredients for the core material and the veneer material are already contained in predicate devices. Additionally, biocompatibility tests were carried out for the core material including stain solution. The results show that LAVA™ is a safe device.

To provide evidence for the effectiveness of the LAVA™ system, the physical and mechanical properties have been compared to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2001

Mr. Andreas Petermann
Regulatory Affairs
3M ESPE AG
ESPE Platz
D-82229 Seefeld Bavaria
GERMANY

Re: K011394
Trade/Device Name: Lava Frame, Lava Frame Shade, Lava Ceram
Regulation Number: 872.6660
Regulatory Class: II
Product Code: EIH
Dated: May 4, 2001
Received: May 7, 2001

Dear Mr. Petermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucento/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K011394

Device Name:

LAVA™ Frame

LAVA™ Frame Shade

LAVA™ Ceram

Indications for Use:

The LAVA™ system is intended for CAD/CAM fabrication of all-ceramic dental restorations.

The system is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Prescription use: ☑ Over-the counter use ☐

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011394